

## **Brief on Appeal to the Board**

Docket No.: **ROBI-4189 (381-2)**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

**Lamberta A. M. Klassen**

Serial No.: **10/805,304**

Filed: **March 22, 2004**

For: **CHILDREN'S TOOTH AND GUM CLEANING KIT**

Group Art Unit: **1744**

Examiner: **KARLS, SHAY LYNN**

### **Real Party of Interest**

The real party of interest in the above mentioned application is 101061967 Saskatchewan Ltd., of Price Albert, Saskatchewan, whereas the inventor Lamberta A. M. Klassen has assigned 100% of the rights in the invention.

### **Related Appeals and Interferences**

There are no related appeals or interferences to this application.

### **Status of Claims**

Claims 1-10, 12, 13, 16, 21-28 and 30-46 are finally rejected and are the subject of this appeal. No other claims are pending.

### **Status of Amendments**

No after final amendment has been filed. All amendments filed have been considered and

are included in the appealed claims.

## **Summary of Claimed Subject Matter**

### **INDEPENDENT CLAIM 1**

The first embodiment is a body support as recited in claim 1 according to the present invention is best depicted and exemplified in Figures 3-9 and is disclosed in paragraphs [0085-0103]. A tooth and gum cleaning kit 1 for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices 8 are configured to be placed upon a finger tip during cleaning. A universal handle 5 having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child. A plurality of omni-directional cleaning tips 10, 12, 14 made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips 10, 12, 14 being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips 10, 12, 14 vary in size, and wherein larger tips include at least one surface feature.

### **DEPENDENT CLAIM 21**

The second embodiment of the present invention is recited in claim 21 that is depicted and exemplified in Figures 12-15. Dependent claim 21 is directed toward a second embodiment of the invention as supported by paragraphs [0095-0110] of the instant specification. A tooth and gum cleaning kit 1 for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices 8 are configured to be placed upon a finger tip during cleaning. A universal handle 5 having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child. A plurality of omni-directional cleaning tips 10, 12, 14 made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips 10, 12, 14 being detachably securable onto the universal handle so as to form a toothbrush for

training children about oral cleaning, wherein the plurality of cleaning tips 10, 12, 14 vary in size, and wherein larger tips include at least one surface feature. The universal handle 5 has a securing mechanism therein for securing and locking any of the plurality of cleaning tips secured onto the universal handle, wherein the securing mechanism 49 can be unlocked with a cam mechanism by pushing a rod 44 from a bottom of the universal handle 5. (see, e.g., pages 4-6 of the instant specification for detailed description of structure embodied in the claims).

### **DEPENDENT CLAIM 23**

The third embodiment of the present invention recited in claim 23 is depicted and exemplified in Figures 12-15. Dependent claim 23 is directed toward a third embodiment of the invention as supported by pages 4-9 of the instant specification. In summary, claim 23 is directed toward a tooth and gum cleaning kit 1 for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices 8 are configured to be placed upon a finger tip during cleaning. A universal handle 5 having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child. A plurality of omni-directional cleaning tips 10, 12, 14 made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips 10, 12, 14 being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips 10, 12, 14 vary in size, and wherein larger tips include at least one surface feature. At least one cleaning tip has a hole in the end of the at least one cleaning tip which would allow a child to breathe through. The universal handle 5 has an unrestricted air passage contained therein whereby , when the at least one cleaning tip is secured onto the universal handle, a diameter of the unrestricted air passage in the universal handle corresponds and cooperates substantially to a diameter of the air passage in the top end of the at least one cleaning tip, which would allow a child to breathe through.

#### **DEPENDENT CLAIM 34**

The forth embodiment of the present invention recited in claim 34 is depicted and exemplified in Figures 59-61. Dependent claim 34 is directed toward a forth embodiment of the invention as supported by pages 4-9 of the instant specification. In summary, claim 34 is directed toward a tooth and gum cleaning kit 1 for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices 8 are configured to be placed upon a finger tip during cleaning. A universal handle 5 having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child. A plurality of omni-directional cleaning tips 10, 12, 14 made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips 10, 12, 14 being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips 10, 12, 14 vary in size, and wherein larger tips include at least one surface feature. Where each of the cleaning tips and the cleaning end portions have a generally oval or elliptical or oblong shape when viewed from a top end of the cleaning tips and the cleaning end portions. When any of the plurality of cleaning tips are secured onto the universal handle 5, a toothbrush is formed, the toothbrush being a powered toothbrush having omni-directional bristles which rotate around a longitudinal axis of the universal handle at a variable or constant or intermittent speed in either direction and/or which vibrate or reciprocate in a longitudinal direction.

#### **DEPENDENT CLAIM 38**

The fifth embodiment of the present invention recited in claim 38 is depicted and exemplified in Figures 10-15. Dependent claim 38 is directed toward a fifth embodiment of the invention as supported by pages 4-9 of the instant specification. In summary, claim 38 is directed toward a tooth and gum cleaning kit 1 for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices 8 are configured to be placed upon a finger tip during cleaning. A universal handle 5

having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child. A plurality of omni-directional cleaning tips 10, 12, 14 made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips 10, 12, 14 being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips 10, 12, 14 vary in size, and wherein larger tips include at least one surface feature. The universal handle 5 has a securing mechanism therein for securing and locking any of the plurality of cleaning tips secured onto the universal handle, wherein the securing mechanism 49 can be unlocked with a cam mechanism by pushing a rod 44 from a bottom of the universal handle 5. The universal handle 5 further comprises a first half portion 37 and a second half portion 38 which are snapped together so as to form the universal handle 5, each of the first half portion 37 and the second half portion 38 having a male protruding ridge 40 on one side and a female receiving slot 41 on the other side which matingly engage the corresponding ridge 40 and slot 41 of the other half portion when snapped together.

#### **INDEPENDENT CLAIM 39**

The sixth embodiment of the present invention recited in claim 39 is depicted and exemplified in Figures 1-9. Independent claim 39 is directed toward a sixth embodiment of the invention as supported by pages 4-7 of the instant specification. In summary, claim 39 is directed toward a tooth and gum cleaning kit 2 for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices 8 having various shaped cleaning end portions produced from a foam cleaning member which is molded or bonded to a flexible sleeve, the flexible sleeve having an integrated finger loop which, when in use, is placed onto a caregiver's finger to provide for oral cleaning of infants and toddlers. A universal toothbrush handle 5 having a middle diameter 30 dimensioned to be held by a child aged 1-4 years old. A first plurality of cleaning tips 10 dimensioned for children aged 1-2 years old. A second plurality of cleaning tips 12 dimensioned for children aged 2-3 years old, said second plurality of cleaning tips have at least one surface feature. A third plurality of cleaning tips 14 dimensioned for children aged 3-4 years old, wherein said third plurality of cleaning tips have at least one surface

feature that includes a bristle, any of the cleaning tips being detachably securable onto the universal toothbrush handle 5 so as to form a toothbrush for effecting the oral cleaning. A portable case 2 for carrying and storing the tooth and gum cleaning devices, the universal handle 5 and the cleaning tips 8, 10, 12, 14.

### **Grounds of Rejection to be Reviewed Upon Appeal.**

Issue 1– Whether claims 1-6, 12, 16, 28 and 31-32 are patentable under 35 USC 103(a) over USPN 6,905,335 to Fischer in view of USPN 6,253,404 to Boland et al in view of USPN 5,765,252 to Carr and further in view of USPN 6,836,917 to Blaustein et al?

Issue 2– Whether claims 1-6, 12, 16, 28, 31-32 and 34-35 are patentable under 35 USC 103(a) over USPN 6,905,335 to Fischer in view of USPN 3,987,549 to Robertelli in view of USPN 5,765,252 to Carr and further in view of USPN 6,836,917 to Blaustein et al?

Issue 3– Whether claims 7-10 and 33 are patentable under 35 USC 103(a) over USPN 6,905,335 to Fischer in view of USPN 6,253,404 to Boland in view of USPN 5,765,252 to Carr and in view of USPN 6,836,917 to Blaustein et al and further in view of USPN 4,406,032 to Diamant; OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above and further in view of USPN 4,406,032 to Diamant?

Issue 4– Whether claims 13 and 23 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,612,770 to Aoyama OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,612,770 to Aoyama?

Issue 5– Whether claims 21-22 and 27 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,745,427 to Trentz OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above further in view of USPN 6,745,427 to Trentz?

Issue 6– Whether claim 24 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,000,410 to Tortorice OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above further in view of USPN 6,000,410 to Tortorice?

Issue 7– Whether claims 25-26 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,000,410 to Tortorice and USPN Application 2004/0161289 to Silberman OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above further in view of USPN 6,000,410 to Tortorice and USPN Application 2004/0161289 to Silberman?

Issue 8– Whether claim 30 is patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 29 above and further in view of USPN 5,392,482 to Drulias OR Fischer, Robertelli, Carr and Blaustein as applied to claim 29 above further in view of USPN 5,392,482 to Drulias?

Issue 9– Whether claim 36 is patentable under 35 USC 103(a) over Fischer, Robertelli, Carr and Blaustein as applied to claim 34 above further in view of USPN 6,253,404 to Boland?

Issue 10– Whether claim 37 is patentable under 35 USC 103(a) over Fischer, Robertelli, Carr, Blaustein and Boland as applied to claim 35?

Issue 11– Whether claim 38 is patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 21 above and further in view of USPN 5,706,545 to Yamada OR Fischer, Robertelli, Carr and Blaustein as applied to claim 21 above and further in view of USPN 5,706,545 to Yamada?

Issue 12– Whether claims 39-40 and 42-44 are patentable under 35 USC 103(a) over Fischer, Boland, Carr, Drulias, and Blaustein?

Issue 13– Whether claims 39-43 are patentable under 35 USC 103(a) over Fischer, Robertelli, Carr, Drulias, and Blaustein?

Issue 14– Whether claims 45-46 are patentable under 35 USC 103(a) over Fischer, Boland, Carr, Drulias, and Blaustein as applied to claim 44 above and further in view of US Publication 2002/0008047 to Hammond OR Fischer, Robertelli, Carr and Drulias as applied to claim 44 above and further in view of US Publication 2002/0008047 to Hammond?

## **Argument**

For each ground of rejection which appellant contests herein which applies to more than one claim, such additional claims, to the extent separately identified and argued below, do not

stand or fall together. Prior to discussing each art rejection appearing below as Issues 1-14, Appellant would first like to bring to the Board's attention the following specific statement made by the Patent Examiner with respect to the claims that "*applicant also amended the claims to include that the limitations that the handle is sized for use by a child and that the brush heads are sized for children aged 1-4 years old.*" The Examiner then states "*these limitations regarding use by a child are considered to be intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since a child is clearly capable of holding the handle of Bolend or Robertelli and the cleaning tips are clearly capable of being used in a child's mouth, then the claim limitations are met by the above references. The claim provides no structural difference between a handle or cleaning tips of a child's toothbrush. Therefore, these limitations are considered intended use and hold no patentable weight.*"

*In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), the Federal Court held that "when an applicant states the meaning that claim terms are intended to have, the claims should be examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." The Federal Court held that the claims should be defined according to the specification, where the Applicant clearly differentiates a handle and tips from the cited art both in its form and function based on its size and specific use. A flexible material for a cleaning tip that is "*made of a flexible material and dimensioned and configured for use within a vestibule of children aged 1-4 years old*" is NOT merely intended use, but defines a specifically made tip for training that would be too small, too soft and unsatisfactory for cleaning adult teeth since it is meant for training on baby teeth and NOT cleaning of permanent adult teeth. The Examiner merely ignored the limitations of the claims and cited art that taught away from the claimed invention based upon "intended use" argument to avoid teaching each and every element of the claims.



**Issue 1– Whether claims 1-6, 12, 16, 28 and 31-32 are patentable under 35 USC 103(a) over USPN 6,905,335 to Fischer in view of USPN 6,253,404 to Boland et al in view of USPN 5,765,252 to Carr and further in view of USPN 6,836,917 to Blaustein et al?**

Independent claim 1 is directed toward a tooth and gum cleaning kit for effecting oral cleaning comprising a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices are configured to be placed upon a finger tip during cleaning. The Examiner cites USPN 5,765,252 to Carr to allegedly teach the finger tip cleaning device. The Carr '252 patent teaches at col. 5, ln. 10 that “*the present invention shown in FIG. 1 is inapplicable for use by children,*” the '252 patent teaches hard bristles and abrasive material for adults to self clean their teeth without a brush. The '252 patent teaches in col. 5, ln. 24-27 that “*the internal diameter of ring 68 is dimensioned to fit around the middle finger of a child. The ring 68 is made of a flexible material so as to accommodate different widths of fingers for different children.*” The Carr '252 teaches that the adult versions are taught to have bristles that are too hard and abrasive and that the body portion is too large for children. Claim 1 finger tip devices are directed toward infants where one skilled in the art and according to the instant specification are to be used on the gums, tongue and cheeks of an infant, whereas while the Carr '252 patent teaches a less rigid and abrasive material it is still only for use on teeth. Furthermore, the children's version is smaller and made to accommodate children's finger sizes. The applicant's instant specification at paragraph [0092] teaches “*the caregiver places their finger (preferably their “pinky” finger) into the sleeve.*”

However, as is well known among those skilled in the art, adults are caregivers for infants and toddlers (ages 0-2), children under the age of 3 have a very limited mental and physical capability and adults clean their teeth with a finger tip brush. The instant invention claims a finger tip placed gum cleaning devices to provide for infants and toddler and NOT for self use by children, but for adults to clean children, because infants of 0-2 years do not have the dexterity or capacity for manually cleaning their own teeth, but are cleaned by an adult care giver to slowly introduce the concept of teeth cleaning to the child. Therefore the infant and toddler finger tip brushes are configured for use by adult for use IN the mouth of an infant and thus it is NOT sized

or configured for use by children as taught in the '252 patent and does not require illustrations to encourage usage. Thus the '252 patent fails to teach the adult sized finger brush configured for a toddler's mouth as claimed by the applicants. Additionally, the configuration of the '252 patent elements are taught to be sized for use with children, just as in the instant invention and one skilled in the art would understand that an apparatus sufficient for an intended purpose in an adult may not be appropriate for children and configured differently structurally and NOT merely an intended use.

A further element of the Applicant's claim 1 is "*a universal handle having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child.*" The Examiner cites USPN 6,836,917 to Blaustein as having "*a handle with an oblong shape when viewed from the bottom (figures 2 and 3 show the dimensions of the handle).*" First, the Blaustein '917 patent has a slight narrowing from the top as shown in FIG. 3, but has an increased thickness at the same portion as shown in the side view of FIG. 2 and thus it clearly DOES NOT have a center with a reduced diameter. Second, the '917 patent is silent regarding use by a child aged 3-4, but is configured only to be held by an adult between the thumb and forefinger, which would NOT be able to be gripped similarly by a child. The applicants' specification details the significant narrowing required for use by a child aged 3-4, which is shown in FIGs. 10 and 11 of the specification. The narrowing of the brush handle must be sufficient enough to allow the child to grasp firmly around the middle and the larger diameter ends are to allow a care giver to place the hand on the brush to assist in training by grasping the ends. The '917 patent is silent regarding the handle of the tooth brush being dimensioned to be held by a child aged 3-4 by sufficient narrowing the center. The Examiner attempts to cure the deficiencies in the references by stating that it is just merely "intended use" to fill in the missing teaching required for a valid prime facie case of obviousness.

The Applicant's claim 1 further includes a plurality of **omni-directional** cleaning tips made of a **flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old**, the plurality of cleaning tips being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips vary in size, and wherein **larger tips include at least one surface feature**. The

applicant claims the features of tips that are “omni-directional,” and “flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old.” The applicants tips are “omni-directional” because they point outward from the center of the tip and are identical in performance despite direction of brush motion so that the smooth, circular rigidged or circular bristled all have the same effectiveness despite direction of use as shown in FIG. 3.

The Examiner alleges that USPN 6,905,335 to Fischer “*teaches a tooth cleaning kit comprising a universal handle and various sized cleaning tips for attaching to the handle.*” The Fisher ‘335 patent best describes the kit taught in the abstract of the specification:

A kit includes a group of predetermined components for enabling a **dental hygienist** or technician to perform non-invasive dental renewal procedures. The kit includes one or more **abrasive devices**, one or more restorative compositions, and one or more **delivery tips for applying the restorative compositions.** The **abrasive device comprises one or more of a low-speed dental bur, a prophylaxis cup, brush, paste or jet.** The kit may also include a delivery device, e.g., a **syringe**, or a storage device for storing the restorative composition. (Emphasis added)

The abstract of the Fischer ‘335 patent clearly teaches away from a children’s cleaning or training kit, does not disclose omni directional tips, nor are the tips made of a flexible material suitable for a children’s vestibule. The contents of the kit of the Fischer ‘335 patent would be known to one skilled in the art to cause death or severe injury to a child if used by a child or even an unskilled adult **within a vestibule of children aged 1-4 years old.** The use of abrasion tips, drills, picks, abrasives, syringes and restorative compounds should not be used by a child within the vestibule (cheek pocket) of children aged 1-4 years old. The kit is directed toward tooth restoration and rarely if ever would tooth restoration equipment be used on the baby teeth of a child aged 0-4 years old unless there was severe tooth decay, which is clearly not for use by other than a dentist or hygienist.

The Fischer ‘355 patent teaches a kit for use by a dental hygienist, not a kit configured for self cleaning. The replaceable tips 26 of the ‘355 patents are taught at column 4, line 50 as a “*means for noninvasively abrading a patient’s tooth, a dental prosthesis, filling material, or other dental work is a low speed dental bur 26.*” The ‘355 patent does not form “a toothbrush” with replaceable tips as required by the Applicant’s claim, but a bit for use in a dental drill. The ‘355 patent fails to provide or teach the applicant’s claimed flexible tips for use within the

vestibule. One skilled in the arts would not confuse the disclosure of the '355 with the applicant's claimed kit as being merely different because of an "intended use."

The Examiner cites USPN 6,253,404 to Boland et al for teaching "*a universal handle (11) and a plurality of cleaning tips (figures 5-6 and 8-9).*" The Boland '404 patent may teach different sized cleaning tips, but none of them are taught to be dimensioned to fit with the mouth of a child aged 1-4 and none of them are omni-directional. Additionally, the toothbrush handle is not narrower in the middle and configured to be used by a child. The '404 patent is silent regarding the special needs of tooth care training in children as the tips must be soft and non-abrasive to prevent damage to a child's vestibule whereas an adult has the knowledge and dexterity to keep rigid bristles in contact with their teeth.

The combination of the Fischer, Boland, Blaustein and Carr references does not teach each and every element of claim 1. Specifically the Fischer patent does not teach a kit configured for self use. The Boland patent does not teach the use of flexible, omni-directional tips configured for use in a child's vestibule. The Blaustein patent fails to teach a toothbrush having a narrower center diameter dimensioned to be self used by a child. The Carr patent does not teach a finger mounted device configured for toddler, but dimensioned to be worn by an adult. In *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984), the Federal Circuit held that it was not enough that the reference disclose all the claimed elements in isolation, but "*the prior art reference must disclose each element of the claimed invention arranged as in the claim.*" As shown above the combination of the art fails to even teach the required elements of independent claim 1, applicant respectfully requests reconsideration and removal of the obviousness rejection of claims 1-6, 12, 16, and 28 in view of the elements of claim 1.

Claim 2 that depends from the kit of claim 1 wherein each of the cleaning tips and the cleaning end portions progress in size from smaller to larger, wherein the at least one surface feature includes grooves. Claim 3 that depends from the kit of claim 1 wherein at least one of the larger cleaning tips has multi directional protrusions and progressively more brush-like shapes. Claim 4 that depends from the kit of claim 1 wherein each of the cleaning tips are characterized by a 360 degree radially outward cleaning surface shape. Claim 5 that depends from the kit of

claim 1 wherein each of the cleaning tips and the cleaning end portions have a generally oval or elliptical or oblong shape when viewed from a top end of the cleaning tips and the cleaning end portions. Claim 6 that depends from the kit of claim 5, wherein each of the cleaning tips and the cleaning end portions have a partially or completely tapered shape toward the top end when viewed from a front and/or side of the cleaning tips and the cleaning end portions. Claim 12 depends from the kit of claim 6, wherein at least one of the cleaning tips has outer surfaces having a partially or completely tapered shape toward the top end when viewed from the front and/or side. Claim 28 depends from the kit of claim 1, whereby non-round final shapes of each of the cleaning tips and the cleaning end portions are manufactured by deformably securing flexible material onto a mandrel which spins around a center axis during material removal. Claim 31 depends from the kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle pattern with an inner surface shape and/or outer bristle shape which is at least partially non-round when viewed from a top end of the toothbrush. Claim 32 depends from the kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle shape with an inner surface shape and/or outer bristle shape which is at least partially tapered when viewed from a front or side of the toothbrush.

Claims 2-6, 12, 28 and 31-32 are directed toward cleaning tips that are NOT taught and NOT obvious because they are all omni-directional, flexible and configured for use within a vestibule of children aged 1-4 years old. The claimed shapes and being configured for use in a child's vestibule are designed to be more effective for preventing injury than cleaning efficiency which is critical during training. The specification teaches at paragraph [0119] *The foam bristles 63 reward the child for "growing up" to a stage which is more like an adult toothbrush, but it does not require them to have the skill of an adult to achieve effective cleaning. Any random movement of the brush by the child will provide cleaning of the teeth as well as the inside of the mouth.*

**Issue 2– Whether claims 1-6, 12, 16, 28, 31-32 and 34-35 are patentable under 35 USC 103(a) over USPN 6,905,335 to Fischer in view of USPN 3,987,549 to Robertelli in view of USPN 5,765,252 to Carr and further in view of USPN 6,836,917 to Blaustein et al?**

Independent claim 1 is directed toward a tooth and gum cleaning kit for effecting oral cleaning comprising a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices are configured to be placed upon a finger tip during cleaning. The Examiner cites USPN 5,765,252 to Carr to allegedly teach the finger tip cleaning device, but is directed toward older children (5 or older) for unsupervised self use. The Carr ‘252 patent teaches at col. 5, ln. 10 that “*the present invention shown in FIG. 1 is inapplicable for use by children,*” the ‘252 patent teaches hard bristles and abrasive material for adults to self clean their teeth without a brush. The ‘252 patent that is directed for use by older children teaches in col. 5, ln. 24-27 that “*the internal diameter of ring 68 is dimensioned to fit around the middle finger of a child. The ring 68 is made of a flexible material so as to accommodate different widths of fingers for different children.*” However, as shown in FIG. 7 it still has bristles, while softer than the adult version is designed to be used on TEETH, whereas toddler and infants have only soft gum and cheeks that are very sensitive and will cause great discomfort because a mouth full of teeth is a different environment from only soft tissues. The Carr ‘252 patent fails to teach the applicant’s embodiment in claim 1.

Independent claim 1 further includes a universal handle having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child. The Examiner alleges that USPN 6,836,917 to Blaustein teaches “*a handle with an oblong shape when viewed from the bottom (figures 2 and 3 show the dimensions of the handle).*” However, claim 1 is not directed toward “*a handle with an oblong shape when viewed from the bottom,*” but a **smaller diameter at the middle** for self use by a child. The Blaustein ‘917 patent has a slight narrowing from the top as shown in FIG. 3, but has an increased thickness at the same portion as shown in the side view of FIG. 2 and thus it clearly DOES NOT have a center with a reduced diameter. The applicants’ specification details the significant narrowing that is required for use by a child aged 3-4, which is shown in FIGs. 10 and 11 of the specification. The

narrowing of the brush handle must be sufficient enough to allow the child to grasp firmly around the middle and the larger diameter ends are to allow a care giver to place the hand on the brush to assist in training by grasping the ends. The '917 patent is silent regarding the handle of the tooth brush being dimensioned to be held by a child aged 3-4 by sufficient narrowing the center.

Independent claim 1 further include a plurality of omni-directional cleaning tips made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips vary in size, and wherein larger tips include at least one surface feature.

The Examiner alleges that USPN 6,905,335 to Fischer *“teaches a tooth cleaning kit comprising a universal handle and various sized cleaning tips for attaching to the handle.”* The Fischer '355 patent as discussed above clearly teaches a kit for use by a dental hygienist, not a kit configured for self cleaning. The replaceable tips 26 of the '335 patents are dental burs for grinding teeth to remove plaque during a dental cleaning as discussed above, not compressible, flexible tips to make a training toothbrush that is appropriate for a child. The mere fact that a kit contains various tips does not teach the applicant's claimed invention.

The Fisher '335 patent best describes the kit taught in the abstract of the specification: A kit includes a group of predetermined components for enabling a **dental hygienist** or technician to perform non-invasive dental renewal procedures. The kit includes one or more **abrasive devices**, one or more restorative compositions, and one or more **delivery tips for applying the restorative compositions**. The **abrasive device comprises one or more of a low-speed dental bur, a prophylaxis cup, brush, paste or jet**. The kit may also include a delivery device, e.g., a **syringe**, or a storage device for storing the restorative composition. (Emphasis added)

The abstract of the Fischer '335 patent clearly teaches away from a kit that is configured for use by child aged 0-4, does not disclose omni directional tips, nor are the tips made of a flexible material suitable for a children's vestibule (cheeks). The contents of the kit would of the Fischer '335 patent would be know to one skilled in the art to cause death or severe injury to a

child if used by a child or even an unskilled adult if used *within a vestibule of children aged 1-4 years old*. The use of abrasion tips, drills, picks, abrasives, syringes and restorative compounds should not be used by a child to clean within the vestibule (cheek pocket) of children aged 0-4 years old and rarely if ever would the equipment be used on the baby teeth of a child aged 0-4 years old unless there was severe tooth decay, which is not for use by other than a dentist or hygienist.

The Examiner alleges that USPN 3,987,549 to Robertelli discloses “a universal handle (12) and a plurality of cleaning tips (figures 2-7) (claim 1).” However, the toothbrush that is taught by the Robertelli ‘549 patent is configured to be held by an adult, NOT a child and the handle taught fails to have a middle diameter smaller than the ends as claimed by the Applicant. The ‘549 patent teaches at col. 2, 23 that “*the motor is preferably a low-inertia high speed D.C. electric motor capable of rotating at a speed up to approximately 10,000 revolutions.*” The ‘549 patent device spinning at 10,000 rpm as disclosed is NOT for self cleaning purposes of and adult or a child, whereas the Applicant claims replaceable tips that are configured and dimensioned to be placed into a vestibule of children aged 1-4 years old. The tips of the ‘549 patent are not configured to fit within and clean the vestibule of children 1-4, but are for removing decayed enamel during dental procedures by a professional.

The Examiner further alleges that the Robertelli ‘549 patent has “*cleaning tips that are characterized by a 360 degree radially outward omni-directional cleaning surface shape (the cleaning tips all have cleaning surfaces that extend 360 from the center)(claim 4).*” The ‘549 patent is silent regarding the “omni-directionality” of their tips, which are not designed or configured to be of a material to contact the vestibule of a 0-4 year old during self use at 10,000 rpm. The disclosed tips are for high speed abrading and polishing and are not of a constructed of a material soft enough to allow for self cleaning by a child because rotation of 10,000 rpm would tear apart the applicant’s claimed cleaning tip. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), the Federal Court held that “*when an applicant states the meaning that claim terms are intended to have, the claims should be examined with that meaning, in order to achieve a complete exploration of the applicant’s invention and its relation to the prior art.*” The applicants specification described omni-directional when viewed in light of the drawings to



mean that any direction that the brush tip had force and movement applied would clean equally well verses a toothbrush having bristles only on one side. The '549 patent is not a proper reference because it is for use by a hygienist with a high speed drill on adult patient's teeth and not on the vestibule of an infant.

The combination of the Fischer, Robertelli, Blaustein and Carr patents does not teach independent claim 1. Specifically the Fischer patent does not teach a kit configured for self use. The Robertelli patent does not teach the use of flexible, omni-directional tips configured for use in a child's vestibule. The Blaustein patent fails to teach a toothbrush having a narrower center diameter dimensioned to be self used by a child. The Carr patent does not teach a finger mounted device configured for toddler, but dimensioned to be worn by an adult. Applicant respectfully requests reconsideration and removal of the obviousness rejection of claims 1-6, 12, 16, 28, 31-32 and 34-35 in view of the arguments directed to claim 1.

Claim 2 that depends from the kit of claim 1 wherein each of the cleaning tips and the cleaning end portions progress in size from smaller to larger, wherein the at least one surface feature includes grooves. Claim 3 that depends from the kit of claim 1 wherein at least one of the larger cleaning tips has multi directional protrusions and progressively more brush-like shapes. Claim 4 that depends from the kit of claim 1 wherein each of the cleaning tips are characterized by a 360 degree radially outward cleaning surface shape. Claim 5 that depends from the kit of claim 1 wherein each of the cleaning tips and the cleaning end portions have a generally oval or elliptical or oblong shape when viewed from a top end of the cleaning tips and the cleaning end portions. Claim 6 that depends from the kit of claim 5, wherein each of the cleaning tips and the cleaning end portions have a partially or completely tapered shape toward the top end when viewed from a front and/or side of the cleaning tips and the cleaning end portions. Claim 12 depends from the kit of claim 6, wherein at least one of the cleaning tips has outer surfaces having a partially or completely tapered shape toward the top end when viewed from the front and/or side. Claim 28 depends from the kit of claim 1, whereby non-round final shapes of each of the cleaning tips and the cleaning end portions are manufactured by deformably securing flexible material onto a mandrel which spins around a center axis during material removal. Claim 31 depends from the kit of claim 5, wherein, when any of the plurality of cleaning tips are

secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle pattern with an inner surface shape and/or outer bristle shape which is at least partially non-round when viewed from a top end of the toothbrush. Claim 32 depends from the kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle shape with an inner surface shape and/or outer bristle shape which is at least partially tapered when viewed from a front or side of the toothbrush.

Claims 2-6, 12, 28 and 31-32 are each separately directed toward cleaning tips that are NOT taught and NOT obvious variations of independent claim 1 because while they are all omnidirectional, flexible and configured for use within a vestibule of children aged 1-4 years old. The claimed shapes are configured for use in a child's vestibule are designed to be more effective for preventing injury than cleaning efficiency which is critical during training, which is NOT taught in the cited combination of references and are NOT merely intended use because the cited art had no intention to prevent injury above and beyond cleaning efficiency. The specification teaches at paragraph [0119] *The foam bristles 63 reward the child for "growing up" to a stage which is more like an adult toothbrush, but it does not require them to have the skill of an adult to achieve effective cleaning. Any random movement of the brush by the child will provide cleaning of the teeth as well as the inside of the mouth.*

**Issue 3– Whether claims 7-10 and 33 are patentable under 35 USC 103(a) over USPN 6,905,335 to Fischer in view of USPN 6,253,404 to Boland in view of USPN 5,765,252 to Carr and in view of USPN 6,836,917 to Blaustein et al and further in view of USPN 4,406,032 to Diamant; OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above and further in view of USPN 4,406,032 to Diamant?**

The combination of the Fischer, Boland, Blaustein and Carr references as previously discussed above in detail does not teach each and every element of independent claim 1. Specifically the Fischer patent does not teach a kit configured for self use, but a kit for a dental hygienist to restore an individual adult's teeth surfaces. The Boland patent does not teach the use

*of flexible, omni-directional tips configured for use in a child's vestibule, but it discloses an electric toothbrush for adults. The Blaustein patent fails to teach a toothbrush having a narrower center diameter dimensioned to be self used by a child only a necked down portion for gripping of substantially the same diameter as shown by FIGs. 1 and 2. The Carr patent teaches the exact opposite of the applicant's claims of a finger mounted device configured for a toddler's mouth, but dimensioned to be worn by an adult to clean. The Court held that "to imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." (See W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). The Examiner fails to form a prima facie case of obvious rely not on the teaching of the references to provide the CLAIMED FEATURES, but improperly dismiss all limitations as intended use.*

*Claim 7 depends from the allowable kit of claim 1 as discussed above wherein each of the cleaning tips and the cleaning end portions are made of a resilient foam. The Examiner cites USPN 4,406,032 to Diamant for teaching "a toothbrush with a head made from a foam rubber (col. 3, lines 64-68)." The teaching of the Diamant '032 patent at col. 3, lines 64-68 states that "the soft member of the toothbrush of the invention which replaces a conventional toothbrush head need not necessarily comprise filamentary material. For example, at least that surface of the soft member which is intended for brushing may consist of **foam rubber or soft rubber**, or other material suitable for that purpose." The Diamant '032 patent does not disclose "resilient foam" as claimed by the applicant NOR does it make up for the deficiencies of the other cited references in teaching each and every element of the claims 1 or 7.*

*Claim 8 depends from the kit of claim 7 wherein at least one of the cleaning tips has a generally planar surface or surfaces. The Examiner cites Robertelli '549 for allegedly teaching that "Robertelli, figure 3 shows the planar surface being located at end of 34 opposite 28)" However, Robertelli teaches that end 34 is a coupling surface to hold the bit into the drill as shown clearly in FIG. 2 and not a cleaning tip surface. Alternatively the Examiner cites Boland '404 for allegedly teaching that "Boland, figure 8A, top and bottom horizontal surface of 80."*

However, the Boland figure 8A violates the omni-directional requirement of the independent base claim 1 because it can not be used in any orientation, whereas the applicants specification have oval shaped tips that allows cleaning in any direction while still having a planar surface. Therefore Boland teaches neither dependent claim 8 or in combination the independent claim 1.

Claim 9 depends from the kit of claim 7 in which at least one of the cleaning tips has raised ridges on a surface thereof. The Examiner cites Boland '404 for allegedly teaching cleaning tips has raised ridges on a surface thereof by "*Boland, figure 6D.*" The Boland reference teaches col. 8, line 19 "*a plurality of depressions,*" and NOT raised ridges. Claim 9, 7 and independent claim 1 are not taught by the cited combinations. Claim 10 depends from the kit of claim 7 wherein at least one of the cleaning tips has raised, generally cylindrical, conical, or flat sided, simulated bristles. The Examiner cites the Robertelli '549 patent for teaches cylindrical bristles in FIG. 3. The cited element of FIG. 3 of the Robertelli '549 patent is an attachment device for the drill and NOT a cleaning tip as shown clearly in FIG. 2.

Claim 33 depends from the kit of claim 32, the toothbrush having radially arrayed bristles in a helical pattern. Claim 32 depends from the kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle shape with an inner surface shape and/or outer bristle shape which is at least partially tapered when viewed from a front or side of the toothbrush. The Examiner admits that while Diamant has a wound filament it would be "obvious to try" when combined with either the Boland or Robertelli references. However, neither would provide the claimed helical head as shown in FIG. 52. The combination of references fails to teach each and every element of claim 32 or independent base claim 1.

The examiner improperly rejects claims 7-10 and 33 as obvious in view of the aforementioned references when further combined with the Diamant '032 patent. Claims 7-10 and 33 depends from allowable independent claim 1 for the reasons discussed previously above, but the addition of the Diamant '032 patent does not teach the missing elements such as a handle having a narrower middle portion configured for children to grasp the toothbrush. Furthermore, the tip of the '032 patent is not taught to be configured and sized for use by a child of age 1-4. Applicant respectfully requests reconsideration and removal of the obviousness rejection of

claims 4-10 and 33, which depend from allowable claim 1.

**Issue 4– Whether claims 13 and 23 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,612,770 to Aoyama OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,612,770 to Aoyama?**

Claims 13 and 23 depends from allowable independent claim 1 for failing to teach each and every element of the base claim for the reasons discussed in full above.

Claim 13 depends from the kit of claim 1 in which at least one cleaning tip has a hole in the **end of the at least one cleaning tip which would allow a child to breathe through**. Claim 23 depends from the kit of claim 13 in which the universal handle has an unrestricted air passage contained therein whereby , when the at least one cleaning tip is secured onto the universal handle, a diameter of the unrestricted air passage in the universal handle corresponds and cooperates substantially to a diameter of the air passage in the top end of the at least one cleaning tip, **which would allow a child to breathe through**. The Examiner alleges that USPN 6,612,770 to Aoyama “teaches a toothbrush comprising a handle with an air passage (8) and cleaning tips (2a-2c) with air holes (9) that corresponds to the diameter of the air passage.” The Examiner admits that “while Aoyama **does not teach using the using the air passage as a means for breathing through**, it is clearly **capable of performing this function**. A recitation of the intended use of the claimed invention **must result in a structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is **capable of performing the intended use**, then it meets the claim.” The Examiner fails to read every limit present in the claim to make it overly broad during interpretation and then claim that it is covered by intended use, but the breathing hole at the END for breathing is not taught only the drying of bristles.

The applicant’s claims 13 and 23 both require that a cleaning tip has a hole in the **end** of the at least one cleaning tip which would allow a **child to breathe through**. The Aoyama ‘770 patent teaches that the hole faces the bristles for air to dry the toothbrush. A child would only need to breathe through the end to prevent choking during panic, which is not capable when the

end of the brush is lodged in the throat and the tooth brush air passages are not open to the throat cavity when the brush end is lodged for example during a fall or if the child was momentarily unattended. *In McGinley v. Franklin Sports Inc.*, 262 F.3d 1339, 60 USPQ2d 1001, 1010 (Fed. Cir. 2001); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A.) where the courts held that references teach away from combination if combination produces seemingly inoperative device. The '770 patent teaches away from the instant claim of a breathing passage because it teaches drying the bristles and the opening is not at the end.

The Aoyama '770 patent is silent regarding the Applicant's claimed universal handle that has a narrower section in the middle to aid in a child gripping the toothbrush. The Aoyama '770 patent also does not teach to dimension and configure the tip end for use in a toothbrush for a 1-4 year old. Claims 13 and 23 are allowable because the combination of references fails to teach each and every element of the claimed invention. Applicant respectfully requests reconsideration and removal of the obviousness rejection of claims 13 and 23.

**Issue 5– Whether claims 21-22 and 27 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,745,427 to Trentz OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above further in view of USPN 6,745,427 to Trentz?**

Claims 21-22 and 27 are allowable for the above previously mentioned reasons for failing to teach each and every limitation of independent claim 1. Claims 21-22 and 27 depend from allowable claim 1. Claim 21 depends from the kit of claim 1 in which the universal handle has a securing mechanism therein for securing and locking any of the plurality of cleaning tips secured onto the universal handle, wherein the securing mechanism can be unlocked with a cam mechanism by pushing a rod from a bottom of the universal handle. Claim 22 depends from the kit of claim 21 in which the universal handle has a deformable button on an outer surface thereof which allows the rod to be pushed axially by a user, the deformable button having sufficient elastic force to return the rod and the securing mechanism to a locked position. Claim 27 depends from the kit of claim 21 in which, when any of the plurality of cleaning tips are to be

secured onto or removed from the universal handle, the securing mechanism requires the cleaning tip to be inserted onto the universal handle and removed from the universal handle at an angle relative to a longitudinal center axis of the universal handle.

The Examiner alleges that USPN 6,745,427 to Trentz teaches a securing mechanism that can be unlocked with a cam mechanism by pushing a rod from the bottom of the handle. The abstract of the Trentz '427 teaches that "*the brush head can be slid onto the brush head holder with a friction fit.*" The Trentz '427 patent fails to teach a cam mechanism that is released by a button, but it is equipped with a ball mechanism. The Trentz '427 patent fails to teach the deficiencies of a handle having a reduced center diameter to be held by a child. The tip is not taught to be sized to fit within the vestibule of a child, but is instead is a toilet cleaning brush. In light of the failure of the '427 reference to address the shortcomings of the combination of references in teaching of independent claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of claims 21-22 and 27.

**Issue 6– Whether claim 24 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,000,410 to Tortorice OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above further in view of USPN 6,000,410 to Tortorice?**

Claim 24 is allowable for the above previously mentioned reasons discussed above for failing to teach each and every element of the base claim. Claim 24 depends from allowable claim 1. Claim 24 of the kit of claim 1, has a universal handle is filled or partially filled with a fluid or combination of fluids that turn different colors or change phase or appearance during prolonged and/or rigorous agitation. The Examiner alleges that USPN 6,000,410 to Tortorice in combination with the Fischer, Boland, Robertelli, Carr and Blaustein references teach each and every element of claim 24, which depends from claim 1. However, the combination fails to teach a brush having a handle with a narrower center portion, an omni-directional tip or flexible tips configured to fit and use within the vestibule of a child aged 1-4.

The Tortice '410 patent teaches a handle, but the diameter is not reduced nor is it taught

to be dimensioned to be held by a child. The tip is not taught to be sized to fit within the vestibule of a child. In light of the failure of the '410 reference to address the shortcomings of the combination of references in teaching claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of claim 24.

**Issue 7– Whether claims 25-26 are patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 1 above and further in view of USPN 6,000,410 to Tortorice and USPN Application 2004/0161289 to Silberman OR Fischer, Robertelli, Carr and Blaustein as applied to claim 1 above further in view of USPN 6,000,410 to Tortorice and USPN Application 2004/0161289 to Silberman?**

Claim 25-26 are allowable for the above previously mentioned reasons for failing to teach each and every element of the independent base claim 1. Claims 25-26 depend from allowable claim 1. Claim 25 directed toward the kit of claim 1, in which the universal handle is filled or partially filled with a foaming fluid or two or more non-emulsifying fluids of different colors and densities which mix together during prolonged and/or rigorous agitation and separate again when the agitation stops. Claim 26 of the kit of claim 25, in which the foaming fluid or two or more non-emulsifying fluids of different colors and densities which fill or partially fill the universal handle are mixed together and combined with one or more agitator objects to increase mixing efficiency. The Examiner alleges that USPN 6,000,410 to Tortorice in further view of USPN Application 2004/0161289 to Silberman when combined with the Fischer, Boland, Robertelli, Carr and Blaustein references teach each and every element of claim 25 and 26, which depends from claim 1. However, the combination fails to teach a brush having a handle with a narrower center portion, an omni-directional tip or flexible tips configured to fit and use within the vestibule of a child aged 1-4.

The Tortice '410 patent and the Silberman '289 patent publications teach a handle, but the center diameter is not reduced nor is it taught to be dimensioned to be held by a child. The tip is not taught to be sized to fit within the vestibule of a child. In light of the failure of the '410 patent and the '289 patent publications reference fails to address the shortcomings of the combination of references in teaching claim 1 the applicant respectfully requests reconsideration



and removal of the obviousness rejections of claims 25 and 26. In light of the failure of the ‘410 reference and the ‘289 patent application to address the shortcomings of the combination of references in teaching claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of claims 25-26.

**Issue 8– Whether claim 30 is patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 29 above and further in view of USPN 5,392,482 to Drulias OR Fischer, Robertelli, Carr and Blaustein as applied to claim 29 above further in view of USPN 5,392,482 to Drulias?**

Claim 30 is allowable over the above cited combination for the above previously mentioned reasons for failing to teach each and every element of independent base claim 1. Claim 30 depends from allowable claim 1. Claim 30 is directed toward the kit of claim 1, wherein the tooth and gum cleaning devices each further comprise a foam cleaning member which is molded or bonded to a flexible sleeve, the flexible sleeve having an integrated finger loop which, when in use, is placed onto the caregiver's finger to provide the oral cleaning of the infants and toddlers. The Examiner alleges that USPN 5,392,482 to “*Drulias teaches a finger brush pad made from a foam material (abstract).*” However, the foam material is shown in FIG. 10 that only covers a small portion and thus it is not omni-directional as required by the claims.

While the Carr ‘252 patent teaches the finger loop, the Drulias ‘482 patent does not teach the whole finger pad being constructed of foam for cleaning an infant’s mouth. In light of the failure of the ‘482 reference to address the shortcomings of the combination of references in teaching claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of claim 30.

**Issue 9– Whether claim 36 is patentable under 35 USC 103(a) over Fischer, Robertelli, Carr and Blaustein as applied to claim 34 above further in view of USPN 6,253,404 to Boland?**

Claim 36 is allowable for the above previously mentioned reasons. Claim 1 is directed toward a tooth and gum cleaning kit for effecting oral cleaning comprising: a series of two or

more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices are configured to be placed upon a finger tip during cleaning; a universal handle having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child; and a plurality of omni-directional cleaning tips made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips vary in size, and wherein larger tips include at least one surface feature. Claim 36 ultimately depends from allowable claim 1 for failing to teach each and every element as discussed above.

Claim 5 depends from the kit of claim 1 wherein each of the cleaning tips and the cleaning end portions have a generally oval or elliptical or oblong shape when viewed from a top end of the cleaning tips and the cleaning end portions. Claim 34 depends from the kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush being a powered toothbrush having omni-directional bristles which rotate around a longitudinal axis of the universal handle at a variable or constant or intermittent speed in either direction and/or which vibrate or reciprocate in a longitudinal direction. Claim 35 depends from the kit of claim 34, wherein the powered toothbrush is operably able to change rotational direction and/or speed and/or pattern or reciprocating amplitude or frequency in response to rotational and/or axial acceleration of the powered toothbrush caused by the user. Claim 36 depends from the kit of claim 35, wherein the powered toothbrush is operably able to rotate a head of the powered toothbrush away from the gums for a number of degrees and then counter rotates the head for a lesser number of degrees.

The Examiner alleges that USPN 6,253,404 to Boland is alleged to teach a toothbrush that rotates as well as oscillates. The Examiner without teaches says that it would be obvious to motivate the Robertelli patent to include that the head oscillates also. The Court held that “*to imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used*

*against its teacher.*” (See *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)). The Examiner fails to form a prima facie case of obviousness and rely not on the teaching of the references to provide the CLAIMED FEATURES, but improperly alleged that it is obvious to try.

The Boland ‘404 patent does not teach a tooth brush handle having a reduced diameter section in the middle. The ‘404 patent is silent regarding tips sized and configured for use by children aged 1-4 years old. In light of the failure of the ‘404 patent reference to address the shortcomings of the combination of references cited in teaching claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of dependent claim 36.

**Issue 10– Whether claim 37 is patentable under 35 USC 103(a) over Fischer, Robertelli, Carr, Blaustein and Boland as applied to claim 35?**

Claim 37 is allowable for the above previously mentioned reasons for failing to teach each and every of the intervening limitations. Claim 37 depends from the kit of claim 36, wherein the universal handle has a graphic or grip pattern characterized by two or more randomly placed generally circular, elliptical or oblong shapes of various sizes connected by substantially straight lines.

Claim 37 ultimately depends from allowable claim 1. In light of the failure of the combination of references to teach each and every element of independent claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of dependent claim 37.

**Issue 11– Whether claim 38 is patentable under 35 USC 103(a) over Fischer, Boland, Carr and Blaustein as applied to claim 21 above and further in view of USPN 5,706,545 to Yamada OR Fischer, Robertelli, Carr and Blaustein as applied to claim 21 above and further in view of USPN 5,706,545 to Yamada?**

Claim 38 is allowable for the above previously mentioned reasons.

Claim 21 depends from the kit of claim 1 in which the universal handle has a securing mechanism therein for securing and locking any of the plurality of cleaning tips secured onto the

universal handle, wherein the securing mechanism can be unlocked with a cam mechanism by pushing a rod from a bottom of the universal handle. Claim 38 depends from the kit of claim 21, wherein the universal handle further comprises a first half portion and a second half portion which are snapped together so as to form the universal handle, each of the first half portion and the second half portion having a **male protruding ridge on one side and a female receiving slot on the other side which matingly engage the corresponding ridge and slot of the other half portion when snapped together.**

The Examiner alleges that USPN 5,706,545 to Yamada teaches “a toothbrush comprising a handle with two halves (14a, 14b). The halves each have male protruding ridges (**not shown, col. 3, lines 55-60**) and **female receiving slots (44)**.” (Emphasis added) The Examiner ignored the applicants claimed male ridge that inserted into a corresponding slot of the other half portion with a TAB AND RECESS (not a slot) that does not use the same leakproof seal and attachment mechanism as claimed. The elimination or broadening of elements still fails to form a prime facie case of obviousness by teaching each and every element as arranged in the claim.

Claim 38 ultimately depends from allowable claim 1. The Yamada ‘545 patent teaches a handle, but the diameter is not reduced nor is it taught to be dimensioned to be held by a child. The tip taught is not taught to be sized to fit within the vestibule of a child. In light of the failure of either of the combination of references to teach each and every element of independent claim 1 the applicant respectfully requests reconsideration and removal of the obviousness rejections of dependent claim 38.

#### **Issue 12– Whether claims 39-40 and 42-44 are patentable under 35 USC 103(a) over Fischer, Boland, Carr, Drulias, and Blaustein?**

Independent claim 39 is directed toward a tooth and gum cleaning kit for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions produced from **a foam cleaning member** which is molded or bonded to a flexible sleeve, the flexible sleeve having an integrated finger loop which, when in use, **is placed onto a caregiver's finger to provide for oral cleaning of infants and toddlers;** a universal toothbrush handle having **a middle diameter dimensioned to be held by a child**

**aged 1-4 years old**; a first plurality of cleaning tips **dimensioned** for children aged 1-2 years old; a second plurality of cleaning tips **dimensioned for children** aged 2-3 years old , said second plurality of cleaning tips have at least one surface feature; a third plurality of cleaning tips **dimensioned for children** aged 3-4 years old, wherein said third plurality of cleaning tips have at least **one surface feature that includes a bristle**, any of the cleaning tips being detachably securable onto the universal toothbrush handle so as to form a toothbrush for effecting the oral cleaning; and a portable case for carrying and storing the tooth and gum cleaning devices, the universal handle and the cleaning tips. Dependent claim 40 is directed toward the kit of claim 39, wherein the series of two or more tooth and gum cleaning devices are designed for infants ages zero to one years old.

The Examiner alleges that USPN 6,905,335 to Fischer “*teaches a tooth cleaning kit comprising a portable case carrying a universal handle and various sized cleaning tips for attaching to the handle.*” The Fisher ‘335 patent best describes the kit taught in the abstract of the specification:

A kit includes a group of predetermined components for enabling a **dental hygienist** or technician to perform non-invasive dental renewal procedures. The kit includes one or more **abrasive devices**, one or more restorative compositions, and one or more **delivery tips for applying the restorative compositions**. The **abrasive device comprises one or more of a low-speed dental bur, a prophylaxis cup, brush, paste or jet**. The kit may also include a delivery device, e.g., a **syringe**, or a storage device for storing the restorative composition. (Emphasis added)

The abstract of the Fischer ‘335 patent clearly teaches away from a children’s cleaning or training kit, does not disclose omni directional tips, nor are the tips made of a flexible material suitable for a children’s vestibule. The contents of the kit of the Fischer ‘335 patent would be known to one skilled in the art to cause death or severe injury to an unskilled adult or **children aged 1-4 years old**. The use of abrasion tips, drills, picks, abrasives, syringes and restorative compounds should not be used by a child within the vestibule (cheek pocket) of children aged 1-4 years old. The kit is directed toward tooth restoration and rarely if ever would tooth restoration

equipment be used on the baby teeth of a child aged 0-4 years old unless there was severe tooth decay, which is clearly not for use by other than a dentist or hygienist. The Examiner merely uses hindsight reasoning and using the applicant own claim as a template to allege the teaching of the reference. The brush does not have a middle diameter handle sized to be held by children.

The Fischer '355 patent teaches a kit for use by a dental hygienist, not a kit configured for self cleaning by either an adult or child. The replaceable tips 26 of the '355 patents are taught at column 4, line 50 as a *“means for noninvasively abrading a patient's tooth, a dental prosthesis, filling material, or other dental work is a low speed dental bur 26.”* The '355 patent does not form “a toothbrush” with replaceable tips as required by the Applicant's claim, but a bit for use in a dental drill. The “toothbrush” of the '355 patent is not configured to be held by a child. Furthermore, the '355 patent does not teach the use of a foam as required by independent claim 39.

The Boland '404 patent teaches different sized cleaning tips, but none of them are taught to be dimensioned to fit with the mouth of a child aged 1-4 nor are they made of foam. Additionally, the toothbrush handle is not dimension in the middle and configured to be used and held by a child. The '404 patent is silent regarding the special needs of tooth care training in children.

The Carr '252 patent teaches the use of cleaning elements that can be placed on the fingertips to clean the teeth of a child. The '252 patent is silent regarding both replaceable tips and a toothbrush with replaceable tips being made of foam to prevent injury or startling of children during initial training.

The Drulias '482 patent does not teach a removable tip attached to a handle. The toothbrush that is disposed over the sleeve are not suitable for toddlers and are NOT made of foam as claimed by the Applicant.

Dependent claim 42 is directed toward the kit of claim 39, wherein the second plurality of cleaning tips are designed for children ages two to three years old by having a surface with a plurality of grooves. Dependent claim 43 is directed toward the kit of claim 39, wherein the third plurality of cleaning tips are designed for children ages three to four years old by having a surface with a plurality of bristles. Dependent claim 44 is directed toward the kit of claim 39, wherein

the portable case further comprises molded cavities integrally formed therein for storage and containment of the two or more tooth and gum cleaning devices, the universal handle and any of the cleaning tips.

The Examiner alleges that the Boland '404 patent teaches the tips of claims 42-44 that are dimensioned for children aged 1-4 having foam brushes with smooth, grooved and bristled surfaces. The Boland '404 patent is silent regarding dimensioning and configuring cleaning tips for young children and does not disclose where the tips are foam of a consistency suitable for tender children's oral cavities. In light of the failure of either of the combination of references to teach each and every element of independent claim 39 the applicant respectfully requests reconsideration and removal of the obviousness rejections of claim 39 and dependent claims 40-44.

**Issue 13– Whether claims 39-43 are patentable under 35 USC 103(a) over Fischer, Robertelli, Carr, Drulias, and Blaustein?**

Independent claim 39 is directed toward a tooth and gum cleaning kit for effecting oral cleaning comprising: a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions produced from a foam cleaning member which is molded or bonded to a flexible sleeve, the flexible sleeve having an integrated finger loop which, when in use, is placed onto a caregiver's finger to provide for oral cleaning of infants and toddlers; a universal toothbrush handle having a middle diameter dimensioned to be held by a child aged 1-4 years old; a first plurality of cleaning tips dimensioned for children aged 1-2 years old; a second plurality of cleaning tips dimensioned for children aged 2-3 years old, said second plurality of cleaning tips have at least one surface feature; a third plurality of cleaning tips dimensioned for children aged 3-4 years old, wherein said third plurality of cleaning tips have at least one surface feature that includes a bristle, any of the cleaning tips being detachably securable onto the universal toothbrush handle so as to form a toothbrush for effecting the oral cleaning; and a portable case for carrying and storing the tooth and gum cleaning devices, the universal handle and the cleaning tips. Dependent claim 40 is directed toward the kit of claim 39, wherein the series of two or more tooth and gum cleaning devices are designed for

infants ages zero to one years old.

The Examiner alleges that USPN 6,905,335 to Fischer “*teaches a tooth cleaning kit comprising a portable case carrying a universal handle and various sized cleaning tips for attaching to the handle.*” The Fischer ‘355 patent teaches a kit for use by a dental hygienist, not a kit configured for self cleaning by either an adult or child as discussed previously above in detail. The replaceable tips 26 of the ‘355 patents are taught at column 4, line 50 as a “*means for noninvasively abrading a patient’s tooth, a dental prosthesis, filling material, or other dental work is a low speed dental bur 26.*” The ‘355 patent does not form “a toothbrush” with replaceable tips as required by the Applicant’s claim, but a bit for use in a dental drill. The “toothbrush” of the ‘355 patent is not configured to be held by a child or for SELF-USE. Furthermore, the ‘355 patent does not teach the use of a foam as required by independent claim 39.

The Carr ‘252 patent teaches the use of cleaning elements that can be placed on the fingertips of a child to clean the teeth of a child, but is silent regarding a fingertip cleaner dimensioned to be worn by a caregiver, but for use in the mouth of an infant. The ‘252 patent is silent regarding both replaceable tips and a toothbrush with replaceable tips being made of foam to prevent injury or startling of children during initial training. The ‘252 patent uses less stiff rubber for self cleaning of an older child’s teeth.

The Drulias ‘482 patent does not teach a removable tip attached to a handle. The toothbrush that is disposed over the sleeve are not suitable for toddlers and are NOT made all of foam as claimed by the Applicant.

Dependent claim 42 is directed toward the kit of claim 39, wherein the second plurality of cleaning tips are designed for children ages two to three years old by having a surface with a plurality of grooves. Dependent claim 43 is directed toward the kit of claim 39, wherein the third plurality of cleaning tips are designed for children ages three to four years old by having a surface with a plurality of bristles. Dependent claim 44 is directed toward the kit of claim 39, wherein the portable case further comprises molded cavities integrally formed therein for storage and containment of the two or more tooth and gum cleaning devices, the universal handle and any of the cleaning tips.



The Examiner further alleges that the Robertelli '549 patent teaches "*a tooth cleaning device comprising a universal handle (12) and a plurality of cleaning tips (figures 2-7). The cleaning tips progress from smaller to larger.*" The '549 patent is silent regarding the whether their tips are made of foam and are not designed or configured to be of a material to contact the vestibule of a 0-4 year old during self use at 10,000 rpm. The disclosed tips are for high speed abrading and polishing and are not of a constructed of a material soft enough to allow for self cleaning by a child because rotation of 10,000 rpm would tear apart the applicant's claimed cleaning tip. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), the Federal Court held that "*when an applicant states the meaning that claim terms are intended to have, the claims should be examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art.*" The applicants specification described child appropriate tips when viewed in light of the drawings to mean that it would fit and be non abrasive to encourage training use. The '549 patent is not a proper reference because it is for use by a hygienist with a high speed drill on adult patient's teeth and not on the vestibule of an infant.

Claim 39 as discussed above is allowable over the prior art for failing to teach each and every element and form a prime facie case of obviousness and claims 40-43 depend from allowable claim 39. Claim 39 distinctly claims that the handle and the replaceable foam tips are dimensioned for use by a child.

The Fischer '355 patent teaches a kit for use by a dental hygienist, not a kit configured for self cleaning by either an adult or child. The replaceable tips 26 of the '355 patents are taught at column 4, line 50 as a "*means for noninvasively abrading a patient's tooth, a dental prosthesis, filling material, or other dental work is a low speed dental bur 26.*" The '355 patent does not form "a toothbrush" with replaceable tips as required by the Applicant's claim, but a bit for use in a dental drill. The "toothbrush" of the '355 patent is not configured to be held by a child. Furthermore, the '355 patent does not teach the use of a foam as required by independent claim 39.

The Robertelli '549 patent discloses an electric toothbrush that is configured to be held by an adult, not a child and the handle taught fails to have a middle diameter smaller than the ends

as claimed by the Applicant. The '549 patent discloses replaceable tips for different cleaning purposes, whereas the Applicant claims replaceable tips that are configured and dimensioned to be placed into a vestibule of children aged 1-4 years old. The tips of the '549 patent are not configured to fit within and clean the vestibule of children 1-4.

The Carr '252 patent teaches the use of cleaning elements that can be placed on the fingertips to clean the teeth of a child. The '252 patent is silent regarding both replaceable tips and a toothbrush with replaceable tips being made of foam to prevent injury or startling of children during initial training.

The Drulias '482 patent does not teach a removable tip attached to a handle. The toothbrush that is disposed over the sleeve are not suitable for toddlers and are NOT made of foam as claimed by the Applicant only the collar 34 is made of foam and it is NOT the cleaning surface.

In *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1595-96 (Fed. Cir.) *Cert. denied*, 481 U.S. 1052 (1987), the Federal Circuit held:

*In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principals or features . . . . The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole."*

The combination of references fails to teach the claimed combination and are merely single elements that fails to motivate one skilled in the art to produce the invention. In light of the failure of either of the combination of references to teach each and every element of independent claim 39 the applicant respectfully requests reconsideration and removal of the obviousness rejections of claim 39 and dependent claims 40-43.

**Issue 14– Whether claims 45-46 are patentable under 35 USC 103(a) over Fischer, Boland, Carr, Drulias, and Blaustein as applied to claim 44 above and further in view of US Publication 2002/0008047 to Hammond OR Fischer, Robertelli, Carr and Drulias as applied to claim 44 above and further in view of US Publication 2002/0008047 to Hammond?**

Claims 45-46 depend from independent claim 39, which is allowed over the cited art. The Hammond publication in combination with the previously discussed art still fails to teach each and every feature of the claimed invention. In light of the failure to teach each and every element of independent claim 39 the Applicant respectfully requests reconsideration and removal of the obviousness rejections of dependent claims 45-46.

## **Conclusion**

For the extensive reasons advanced above, Appellant respectfully but forcefully contends that each and every claim is patentable. Therefore, appellant prays for reversal of all rejections, which is courteously solicited.

Respectfully submitted,  
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## Claims Appendix

1. A tooth and gum cleaning kit for effecting oral cleaning comprising:

a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions able to provide for oral cleaning of infants and toddlers wherein said series of two or more gum cleaning devices are configured to be placed upon a finger tip during cleaning;

a universal handle having a middle and ends, with a smaller diameter at the middle than the ends and configured for self use by a child; and

a plurality of omni-directional cleaning tips made of a flexible material dimensioned and configured for use within a vestibule of children aged 1-4 years old, the plurality of cleaning tips being detachably securable onto the universal handle so as to form a toothbrush for training children about oral cleaning, wherein the plurality of cleaning tips vary in size, and wherein larger tips include at least one surface feature.

2. The kit of claim 1 wherein each of the cleaning tips and the cleaning end portions progress in size from smaller to larger, wherein the at least one surface feature includes grooves.

3. The kit of claim 1 wherein at least one of the larger cleaning tips has multi directional protrusions and progressively more brush-like shapes.

4. The kit of claim 1 wherein each of the cleaning tips are characterized by a 360 degree radially outward cleaning surface shape.

5. The kit of claim 1 wherein each of the cleaning tips and the cleaning end portions have a generally oval or elliptical or oblong shape when viewed from a top end of the cleaning tips and the cleaning end portions.

6. The kit of claim 5, wherein each of the cleaning tips and the cleaning end portions have a partially or completely tapered shape toward the top end when viewed from a front and/or side of the cleaning tips and the cleaning end portions.

7. The kit of claim 1 wherein each of the cleaning tips and the cleaning end portions are made of a resilient foam.

8. The kit of claim 7 wherein at least one of the cleaning tips has a generally planar surface or surfaces.

9. The kit of claim 7 in which at least one of the cleaning tips has raised ridges on a surface thereof.

10. The kit of claim 7 wherein at least one of the cleaning tips has raised, generally cylindrical, conical, or flat sided, simulated bristles.

11 (Cancelled)

12. The kit of claim 6, wherein at least one of the cleaning tips has outer surfaces having a partially or completely tapered shape toward the top end when viewed from the front and/or side.

13. The kit of claim 1 in which at least one cleaning tip has a hole in the end of the at least one cleaning tip which would allow a child to breathe through.

14-15. (Cancelled)

16. The kit of claim 1 wherein the universal handle is substantially oval or elliptical or oblong when viewed from a top or bottom of the universal handle.

17-20. (Cancelled)

21. The kit of claim 1 in which the universal handle has a securing mechanism therein for securing and locking any of the plurality of cleaning tips secured onto the universal handle, wherein the securing mechanism can be unlocked with a cam mechanism by pushing a rod from a bottom of the universal handle.

22. The kit of claim 21 in which the universal handle has a deformable button on an outer surface thereof which allows the rod to be pushed axially by a user, the deformable button having sufficient elastic force to return the rod and the securing mechanism to a locked position.

23. The kit of claim 13 in which the universal handle has an unrestricted air passage contained therein whereby, when the at least one cleaning tip is secured onto the universal handle, a diameter of the unrestricted air passage in the universal handle corresponds and cooperates substantially to a diameter of the air passage in the top end of the at least one cleaning tip, which would allow a child to breathe through.

24. The kit of claim 1, in which the universal handle is filled or partially filled with a fluid or combination of fluids that turn different colors or change phase or appearance during prolonged and/or rigorous agitation.

25. The kit of claim 1, in which the universal handle is filled or partially filled with a foaming fluid or two or more non-emulsifying fluids of different colors and densities which mix together during prolonged and/or rigorous agitation and separate again when the agitation stops.

26. The kit of claim 25, in which the foaming fluid or two or more non-emulsifying fluids of different colors and densities which fill or partially fill the universal handle are mixed together and combined with one or more agitator objects to increase mixing efficiency.

27. The kit of claim 21 in which, when any of the plurality of cleaning tips are to be secured onto or removed from the universal handle, the securing mechanism requires the cleaning tip to be inserted onto the universal handle and removed from the universal handle at an angle relative to a longitudinal center axis of the universal handle.

28. The kit of claim 1, whereby non-round final shapes of each of the cleaning tips and the cleaning end portions are manufactured by deformably securing flexible material onto a mandrel which spins around a center axis during material removal.

29. (Canceled)

30. The kit of claim 1, wherein the tooth and gum cleaning devices each further comprise a foam cleaning member which is molded or bonded to a flexible sleeve, the flexible sleeve having an integrated finger loop which, when in use, is placed onto the caregiver's finger to provide the oral cleaning of the infants and toddlers.

31. The kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle pattern with an inner surface shape and/or outer bristle shape which is at least partially non-round when viewed from a top end of the toothbrush.

32. The kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush having conventional bristles having a radially outward 360 degree bristle shape with an inner surface shape and/or outer bristle shape which is at least partially tapered when viewed from a front or side of the toothbrush.

33. The kit of claim 32, the toothbrush having radially arrayed bristles in a helical pattern.



34. The kit of claim 5, wherein, when any of the plurality of cleaning tips are secured onto the universal handle, a toothbrush is formed, the toothbrush being a powered toothbrush having omni-directional bristles which rotate around a longitudinal axis of the universal handle at a variable or constant or intermittent speed in either direction and/or which vibrate or reciprocate in a longitudinal direction.

35. The kit of claim 34, wherein the powered toothbrush is operably able to change rotational direction and/or speed and/or pattern or reciprocating amplitude or frequency in response to rotational and/or axial acceleration of the powered toothbrush caused by the user.

36. The kit of claim 35, wherein the powered toothbrush is operably able to rotate a head of the powered toothbrush away from the gums for a number of degrees and then counter rotates the head for a lesser number of degrees.

37. The kit of claim 36, wherein the universal handle has a graphic or grip pattern characterized by two or more randomly placed generally circular, elliptical or oblong shapes of various sizes connected by substantially straight lines.

38. The kit of claim 21, wherein the universal handle further comprises a first half portion and a second half portion which are snapped together so as to form the universal handle, each of the first half portion and the second half portion having a male protruding ridge on one side and a female receiving slot on the other side which matingly engage the corresponding ridge and slot of the other half portion when snapped together.

39. A tooth and gum cleaning kit for effecting oral cleaning comprising:

a series of two or more tooth and gum cleaning devices having various shaped cleaning end portions produced from a foam cleaning member which is molded or bonded to a flexible sleeve, the flexible sleeve having an integrated finger loop which, when in use, is placed onto a caregiver's finger to provide for oral cleaning of infants and toddlers;

a universal toothbrush handle having a middle diameter dimensioned to be held by a child aged 1-4 years old;

a first plurality of cleaning tips dimensioned for children aged 1-2 years old;

a second plurality of cleaning tips dimensioned for children aged 2-3 years old, said second plurality of cleaning tips have at least one surface feature;

a third plurality of cleaning tips dimensioned for children aged 3-4 years old, wherein said third plurality of cleaning tips have at least one surface feature that includes a bristle, any of the cleaning tips being detachably securable onto the universal toothbrush handle so as to form a toothbrush for effecting the oral cleaning; and

a portable case for carrying and storing the tooth and gum cleaning devices, the universal handle and the cleaning tips.

40. The kit of claim 39, wherein the series of two or more tooth and gum cleaning devices are designed for infants ages zero to one years old.

41. The kit of claim 39, wherein the first plurality of cleaning tips are designed for children ages one to two years old by having a smooth surface.

42. The kit of claim 39, wherein the second plurality of cleaning tips are designed for children ages two to three years old by having a surface with a plurality of grooves.

43. The kit of claim 39, wherein the third plurality of cleaning tips are designed for children ages three to four years old by having a surface with a plurality of bristles.

44. The kit of claim 39, wherein the portable case further comprises molded cavities integrally formed therein for storage and containment of the two or more tooth and gum cleaning devices, the universal handle and any of the cleaning tips.

45. The kit of claim 44, wherein the kit further comprises a compact disc with computer instructions, and a laminated instruction card, for directions as to proper use of the kit, the compact disc and the laminated instruction card being stored and contained in the portable case.

46. The kit of claim 45, wherein the kit further comprises a tube of toothpaste.

**Evidence Appendix**

None.

**Related Proceedings Appendix**

None.